DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie (US Patent No. 6,635,008) in view of Waksman et al. (US Patent No. 7,160,238) and further in view of Liprie (US Patent No. 5,800,333) and further in view of Meloul et al. (US Patent No. 6,013,020). Liprie'008 discloses the device substantially as claimed including: a transfer device usable in a system for intraluminal treatment of a selected site in a body of a patient (Fig. 2) by a source train of treating elements (Fig. Ia, 19; col. 6, lines 60-62 discloses that the treating elements may also comprise a plurality of radioactive seeds, therefore comprising a source train) advanced through a lumen in the transfer device (Fig. 3, 56) into a lumen of a separate catheter (24), the transfer device being adapted to receive a source cartridge (30) for storing the source train of treating

elements, a system for preventing operation of the transfer device unless each of the catheter and source cartridge are attached thereto, said systems comprising at least one microprocessor (col. 2, lines 13-17); said system for preventing operation of the transfer device (col. 8, lines 6-22) comprising: an illumination source and optical sensor located in the transfer device in proximity to where each of the catheter source cartridge is received by the transfer device, each illumination source being located with respect to its optical sensor so that the optical sensor is able to receive light from its illumination source only if the catheter, fluid cartridge or source cartridge is not received by the transfer device, and the optical sensor being blocked from receiving light from the illumination source when the catheter, fluid cartridge or source cartridge are received by the transfer device (col. 7, line 64 through col. 8, line 5); at least one microprocessor for controlling the movement of the treating element from the transfer device to the catheter (col. 2, lines 13-17), the microprocessor preventing operation of the transfer device upon receiving a signal from any of the optical sensors indicating that at least one of the catheter, fluid cartridge and source cartridge is not attached to the transfer device (col. 8, lines 6-22).

Liprie '008, however, does not specifically disclose that the treating element is advanced through the transfer device by means of pressurized fluid. Waksman, however, discloses that it is common within the art to advance radioactive treating elements through the lumen of a catheter by means of a pressurized fluid (abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have known to use Liprie '008's device with a pressurized fluid

source/cartridge as taught by Waksman (Fig. 1, 14; Fig. 2, 40) in order to move the treating element from the transfer device into a catheter lumen and to the treatment site.

Liprie '008 in view of Waksman, however, do not disclose a graphical interface controlled by the microprocessor. Liprie '333, however, discloses a sensor that senses whether or not the transport tube is attached. If the transport tube is not attached, the operation of the transport device is prevented and an error message with a code number is displayed on the display (col. 8, lines 4-21). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Liprie '008 in view of Waksman with the sensor and display message, as taught by Liprie '333, in order to provide a system that allows the user to understand why the operation of the system is .prevented and how to fix the problem.

While Liprie '008 discloses an optical sensor system for determining whether the catheter, fluid cartridge and source cartridge are within the transfer device, Liprie does not disclose a system for determining if one or more of the treating elements are missing from the source cartridge using optical sensors. Meloul, however, discloses a system for determining if one or more of the treating elements is missing from the source cartridge in the transfer device (col. 3, lines 10-24; col. 32, lines 1-10 disclose that the optical system can also be designed to detect two gold marker seeds which therefore when detected indicate that all treating elements between the seeds are in the device, and if the second gold marker seed is not detected, then at least one or more of the treating elements is missing) comprising: a light source including a jacketed fiber optic bundle disposed on a first side of the storage sleeve to produce a plane of light, a

first slot disposed in the first side of the source cartridge, wherein said plane of light is directed towards said first slot; a linear array of photo sensors disposed on second side of the source cartridge, a second slot disposed in the second side of the source cartridge, wherein said photo sensors measure light from the light source that travels through said second slot; at least one microprocessor for comparing the amount of light measured by the photo sensors to a reference amount corresponding to the amount of light measured by the photo sensors when one or more of the treating elements is not within the lumen of the source cartridge, wherein the plane of light shines through the first slot, the storage cartridge and the second slot and is received by the photo sensor when one or more of the treating elements is not within the source cartridge, and wherein if some treating elements are within the source cartridge but one or more of the treating elements is missing from the source cartridge, a portion of the plane of light will shine through the first slot, the source cartridge and the second slot and be received by the photo sensors, the microprocessor then being able to determine based on the amount of light received by the photo sensors that one or more of the treating elements is missing (col. 31, lines 35-67 and col. 32, lines 1-33). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Liprie in view of Waksman and further in view of Liprie, in order to provide a treatment system which allows the user to verify that all treating elements are accounted for, as taught by Meloul, for the purposes of quality assurance as well as for the purpose calculating treatment, so it is not assumed that the correct number of treating elements

were delivered when in fact some were missing, thereby resulting in a less effective treatment.

While Meloul discloses that other orientations of the light sources and the photosensors may be used (col. 22, lines 4-7), Meloul does not specifically discloses that the photosensors are on the opposite side from the first side of the source cartridge. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Meloul to place the photosensors on the opposite side from the first side of the source cartridge, as Meloul discloses that other orientations of the light sources and the photosensors are possible and may be used in Meloul's device.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman et al. (US Patent No. 7,160,238) in view of Spako et al. (US Patent no. 5,103,395) and further in view of Meloul et al. (US Patent No. 6,013,020). Waksman discloses the device substantially as claimed including: a transfer device (Fig. 2a) usable in a system for intraluminal treatment of a selected site in a body of a patient by at least one treating element advanced from a translucent Storage sleeve (52) having a lumen into a lumen of a separate catheter (Fig. 1, "catheter") by means of pressurized fluid (abstract). Waksman, however, does not disclose a system for detecting the presence or absence of one or more of the treating elements. Spako, however discloses a system for detecting the presence or absence of the treating element in the

translucent storage sleeve comprising; a light source including a jacketed fiber optic bundle disposed on a first side of the storage sleeve to produce a plane of light that intersects at least a portion of the storage sleeve lumen; a linear array of photo sensors disposed on a second side of the storage sleeve so as to measure light from the light source; a microprocessor for' comparing the amount of light measured by the photo sensors to a reference amount corresponding to the amount of light measured by the photo sensors when the treating element is not within the lumen of the storage sleeve (col. 12, lines 67 through col. 13, line 65). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Waksman's device with the sensors, as taught by Spako, in order to determine whether or not the treating element was in place before treatment. ,

Waksman in view of Spako, however, does not disclose means for detecting whether some of the treatment elements are missing from the storage sleeve. Meloul, however, discloses a way of detecting whether, some, none or all of the treating elements are within the storage sleeve (col. 3, lines 10-24 and col. 31, lines 48-60 and col. 32, lines 1-10 disclose that that the optical system can also be designed to detect two gold marker seeds which therefore when detected indicate that all treating elements between the seeds are in the device, and if the second gold marker seed is not detected, then at least one or more of the treating elements is missing). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Waksman in view of Spako and further in view of Meloul, in order to provide a treatment system which allows the user to verify that all treating elements are

accounted for, for the purposes of quality assurance as well as for the purpose calculating treatment, so it is not assumed that the correct number of treating elements were delivered when in fact some were missing, thereby resulting in a less effective treatment.

While Meloul discloses that other orientations of the light sources and the photosensors may be used (col. 22, lines 4-7), Meloul does not specifically discloses that the photosensors are on the opposite side from the first side of the source cartridge. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Meloul to place the photosensors on the opposite side from the first side of the source cartridge, as Meloul discloses that other orientations of the light sources and the photosensors are possible and may be used in Meloul's device.

Response to Arguments

Applicant's arguments filed 5/9/2008 have been fully considered but they are not persuasive. The examiner has reviewed Applicant's arguments and agrees that Meloul does not explicitly disclose that the photosensors are disposed on the opposite side of the source cartridge from the first side of the source cartridge, however, as added to the rejection above and as explained above, a passage in Meloul discloses that there are other orientations of the light sources and photosensors possible, and it is the examiner's position that it would have been obvious to place the photosensors on the

opposite side of the cartridge, as it is merely another orientation of the light source and photosensors, which Meloul discloses many of which are possible.

The examiner also acknowledges the fact that in the last office action that was mailed on 1/10/2008, the examiner in the response to arguments section of the office action, mistakenly stated that "Waksman in view of Spako and further in view of Meloul still anticipated claims 20-22". Applicant correctly pointed out that this was an obviousness rejection and therefore Waksman in view of Spako in view of Meloul did not anticipate claims 20-22, instead they rendered claims 20-22 obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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